

**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks

**Status of the Claims**

Claims 2, 9-10, 12-15, 28 and 31-34 are now present in this application. Claims 2, 32 and 34 are independent.

Claims 3-8, 11, 16-27 and 30 were previously canceled without prejudice or disclaimer of the subject matter contained therein. Claim 29 has been canceled herein. Claims 32-34 have been added, and claim 2 has been amended.

No new matter has been added with the present amendments and new claims. Claim 2 has support in the specification at, e.g., paragraphs [0012], [0044]-[0048] and [0050]. Also, Formula [4] of claim 2 is a chemical structural formula showing a structure which is common to a part of the polymer described in paragraph [0053] of the specification. Support for the new claims is found in the other pending claims and throughout the present specification. Applicants also note the discussion below under "New Claims" starting on page 13.

Entry of these claim amendments is respectfully requested.

Reconsideration of this application, as amended, is also respectfully requested.

**Priority under 35 U.S.C. § 119**

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. § 119, and receipt of the certified priority document (page 2 of Office Action).

**Rejection Under 35 U.S.C. § 112, 1st Paragraph (Enablement and/or Written Description)**

Claims 2, 9-10, 12-15, and 28-29 stand rejected under 35 U.S.C. § 112, 1st Paragraph. This rejection is respectfully traversed. A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

In the Office Action, the Examiner refers to the following issues:

- (1) The specification does not support the recited attachment of the polymer chains claimed with the DLC via covalent bonds;
- (2) Claim 28 recites "a polymer of hydrophilic 2-hydroxypropyl methacryl amide", and thus assertedly improperly depends on claim 2; and
- (3) Claim 29 recites an ester linkage, which does not have sufficient support in the present specification.

"The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention on any ground is always upon the examiner." *Ex parte Parks*, 30 USPQ2d 1234, 1236 (citing *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992)); *see also In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). Also, Applicants the primary consideration here is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Applicants respectfully submit that this initial burden has not been met, and that the one of skill in the art would understand that Applicants were in possession of the claimed invention (at the time of filing).

Regarding issue (1), Applicants respectfully refer the Examiner to the present specification, paragraph [0044], which states that "various organic components can be grafted to

the surface of the DLC film by graft-polymerizing various radical-polymerizable monomers on the activated surface of the DLC film.” Paragraph [0044] also describes how radical-polymerizable monomers are graft-polymerized to the DLC surface, and then the addition-polymerizable vinylmonomers of one of the claimed formulas binds (graft-polymerizes) to the radical-polymerizable monomers.

Further, Applicants respectfully submit that the proper perspective for this issue under 35 U.S.C. § 112, first paragraph, is from one having skill in the art. In fact, an exact, verbatim description is not necessary. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). In addition, a “patent need not teach, and preferably omits, what is well known in the art.” *See, Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987); *Hybritech v. Monoclonal Antibodies*, 802 F. 2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987). In this regard, Applicants note the state of the art. Specifically, it is a commonly known that a graft polymerization forms a graft polymer chain covalently bonded to a main polymer. For example, Chapter 3.2.5 “Graft Polymerization” at page 69 of the *Surface Engineering of Polymer Membranes* (Zhihang Xu, Xiaojun Huang, Lingshu Wan, ISBN 7308061698, 9787308061698, Springer (2009))<sup>1</sup> describes:

Surface grafting is a chemical modification method. In surface graft polymerization, the modification is achieved by tethering suitable macromolecular chains on the membrane surface through covalent bonding.”

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<sup>1</sup> Please find this reference in Google books at:  
[http://books.google.com/books?id=A9EjCjKKgg8C&printsec=frontcover&dq=zhikang+xu&hl=en&ei=tmB1TMz0DsH98AaB\\_5yyBw&sa=X&oi=book\\_result&ct=result&resnum=1&ved=0CCsQ6AEwAA#v=onepage&q&f=false](http://books.google.com/books?id=A9EjCjKKgg8C&printsec=frontcover&dq=zhikang+xu&hl=en&ei=tmB1TMz0DsH98AaB_5yyBw&sa=X&oi=book_result&ct=result&resnum=1&ved=0CCsQ6AEwAA#v=onepage&q&f=false)

Applicants also note FIG. 3.3 on the same page 69 of *Surface Engineering of Polymer Membranes*.

Similarly, in the *Handbook on the Physics and Chemistry of Rare Earths* (Karl A. Gschneidner, Jean-Claude G. Bünzli, Vitalij K. Pecharsky, Vol. 36, Elsevier, 2006, ISBN 0444521429, 9780444521422)<sup>2</sup> at page 356, line 16, this textbook describes: “[g]raft polymerization can be used to modify the substrate polymer and improve its properties. No phase separation of the two polymers is possible by the grafting process, because by grafting the polymer side chain is covalently linked to the back bone.”

Thus, the state of the art supports Applicants’ position that one of skill in the art clearly understands that when graft polymerization is performed by using a polymerization starting point which are radicals or the like formed on the surface of the DLC film, then “one end of the polymer chain is covalently bonded to the surface of the diamond-like carbon film.”

Therefore, Applicants respectfully submit that the present specification as well as the state of the art sufficiently and fully describe the disputed claims, that a skilled artisan would have understood the inventors to be in possession of the claimed invention at the time of filing, and the instant claims fully comply with the provisions of 35 U.S.C. § 112, first paragraph.

Regarding issue (2), claim 2 has been amended as shown herein. Therefore, the polymer chain of claim 28 is included into the polymer chain of claim 2. And as discussed above, grafting and covalent bonding are sufficiently described in the present specification. Applicants also note paragraph [0053] of the present specification.

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<sup>2</sup> Please find this reference in Google books at:

Regarding issue (3), claim 29 has been canceled, thereby rendering the rejection of this claim moot.

Based on the above, reconsideration and withdrawal of this rejection are respectfully requested.

**Rejections under 35 U.S.C. § 103(a)**

Claims 2, 12-15 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Pacetti '602** (U.S. Patent No. 7,033,602) in view of **New '475** (U.S. 2004/127475), and further in view of **Dang '531** (U.S. Patent No. 6,159,531).

Also, claims 9-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Pacetti '602, New '475, Dang '531** and further in view **Lemelson '570** (U.S. Patent No. 6,083,570).

Further, claim 28 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over **Pacetti '602, New '475, Dang '531** and further in view **Pacetti '936** (U.S. 2005/0070936).

Applicants respectfully traverse. Reconsideration and withdrawal of each of these rejections are respectfully requested.

A complete discussion of the Examiner's rejections is set forth in the Office Action, and is not being repeated herein.

**Applicable U.S. Case Law**

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383

U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 sets forth some rationales that were set established in the recent decision of *KSR Int'l Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

Applicants respectfully submit that the *Graham* factors weigh in Applicants' favor, and that a proper rationale has not been set forth in forming the outstanding rejections.

#### Improper Combinations of References

Claims 2 and 32 recite, *inter alia*, "the biocompatible component and the surface of the diamond-like carbon film are bonded to each other without a linker." The Examiner admits that neither Pacetti '602 nor New '475 teaches covalent bonding (see page 5, line 12 of the Office Action). Dang '531 fails to teach that a bioactive/biocompatible agent is covalently linked without using multifunctional linkers. Therefore, the inventions of claims 2 and 32 are patentably distinct over the cited combination of Pacetti '602, New '475 and Dang '531.

Furthermore, Dang '531 fails to show or describe a DLC film. Dang '531 shows that "[t]he plasma deposition step 17 used to achieve activation of the surface utilizes precursor gases" (see column 2, line 59 of Dang '531). Dang '531 shows that "[b]y using allylamine, the desire is to have radicals created by the plasma occurring preferentially at C=C double bonds so

that the free amine groups created are preserved for other reactions as hereinafter described” (see column 3, line 49 of Dang ‘531). Therefore, it is clear that no DLC film is formed in the plasma deposition step 17 of Dang ‘531. Dang ‘531 fails to bond a bioactive/biocompatible agent to the DLC film. In this regard, and as the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* M.P.E.P. § 2143.03.

Even if, *arguendo*, Pacetti ‘602, New ‘475, and Dang ‘531 were somehow combined with one another, one of ordinary skill in the art would not realize or be taught the feature that “a biocompatible component covalently bonded to a surface of the diamond-like carbon film”. Therefore, the inventions of claims 2 and 32 are patentable, and the *Graham* factors weigh in Applicants’ favor, and that a proper rationale has not been set forth in forming the outstanding rejection.

Regarding the second rejection, as explained on pages 6-7 of the Office Action, the Examiner cites Lemelson ‘570 to disclose the intermediate layer of pending claims 9 and 10. Applicants note that these claims depend on claim 2, wherein these dependent claims are patentable for the same reasons stated herein. The further citation of Lemelson ‘570 does not make the initial combination of Pacetti ‘602, New ‘475, and Dang ‘531 any more proper.

Regarding the third rejection, as explained on pages 7-8 of the Office Action, the Examiner cites Pacetti ‘936 to disclose the 2-hydroxypropyl methacryl amide of pending claim 28. Instantly pending claim 28 recites, *inter alia*, “the biocompatible component is a polymer of 2-hydroxypropyl methacryl amide.” The Examiner states that Pacetti ‘936 shows a coating including a polymer of 2-hydroxypropyl methacryl amide. However, Pacetti ‘936 shows a

polymer including copolymer of derivatives of EVAL (ethylene and vinyl alcohol) (see paragraph [0007] of Pacetti '936). The 2-hydroxypropyl methacryl amide is included in part of the derivatives of EVAL to improve the characteristic of the EVAL, and is integrally formed with the EVAL. The EVAL is inevitable for Pacetti '936, and cannot be separated from the 2-hydroxypropyl methacryl amide. Pacetti '936 fails to teach a stent on which a polymer of 2-hydroxypropyl methacryl amide is coated. If anything, this is a teaching away.

#### New Claims

Claims 31 and 33 depend from claims 2, and 32, respectively. Therefore, the inventions of claims 31 and 33 are patentably distinct from the cited combinations of references for the reasons stated herein. Each of claims 31 and 33 recites, *inter alia*, “a carbon atom of one end of the polymer chain and a carbon atom of the diamond-like carbon film are directly bonded to each other.” None of references of Pacetti '602, Pacetti '936, New '475, and Dang '531 teaches such a feature. Therefore, in this regard, claims 31 and 33 are also patentable.

Furthermore, it is clear that if graft polymerization is performed by use of a polymerization starting point which are radicals or the like formed on the surface of the DLC film, “a carbon atom of one end of the polymer chain and a carbon atom of the diamond-like carbon film are directly bonded to each other.” Therefore, no new matter has been added in claims 31 and 33.

Claim 34 recites, *inter alia*, “the diamond-like carbon film has oxygen atoms bonded to carbon atoms of the diamond-like carbon film, and a part of the oxygen atoms is included in a hydroxyl group and another part of the oxygen atoms except the hydroxyl group are bonded to

the biocompatible component.” None of the references of Pacetti ‘602, Pacetti ‘936, New ‘475, and Dang ‘531 teaches such a feature. Introducing a hydroxyl group into a DLC film is described in paragraphs [0059] and [0087] of the present specification. Oxygen included in the hydroxyl group is clearly bonded to carbon included in the DLC film from its production mechanism. Also, introducing a biocompatible polymer by reaction of a hydroxyl group is described in, e.g., paragraph [0060] of the specification. Therefore, no new matter has been added in claim 34.

Based on the present amendments and arguments, reconsideration and withdrawal of all rejections are respectfully requested.

### **Conclusion**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant(s) therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Registration No.

48501 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

AUG 26 2010

Dated: \_\_\_\_\_

Respectfully submitted,

By \_\_\_\_\_  
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